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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/250,883	02/16/1999	JOHN C. RUSSELL	6131.US.02	2585

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ABBOTT LABORATORIES
DEPT. 377 - AP6D-2
100 ABBOTT PARK ROAD
ABBOTT PARK, IL 60064-6050

EXAMINER	
MYERS, CARLA J	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 07/30/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/250,883	Applicant(s) RUSSELL ET AL.	
	Examiner Carla Myers	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. This action is in response to Paper No. 26, filed March 20, 2002. Applicants arguments presented in the response of Paper No. 26 have been fully considered but are not persuasive to overcome all grounds of rejection. This action is made final.

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 25-34 are rejected under 35 U.S.C. 101 because the claimed invention lacks a credible, substantial, specific or well-established utility.

The claims are drawn to polynucleotides comprising a sequence selected from the group consisting of SEQ ID NO: 1-14. The claimed polynucleotides are not supported by either a specific and substantial asserted utility or a well-established utility. The specification fails to provide objective evidence of any activity for the claimed polynucleotides or to show that polynucleotides having the stated consensus sequence of SEQ ID NO: 14 even exist. The specification teaches that a consensus sequence derived from SEQ ID NO: 1-13 hybridizes to ESTs in 27% of breast tissue samples, whereas the consensus sequence only hybridizes to ESTs in 3.4% of non-breast tissue samples. Based on this information, the specification concludes that the individual sequence fragments of SEQ ID NO: 1-13 and the consensus sequence of SEQ ID NO: 14 are useful in "detecting, diagnosing, staging, monitoring, prognosticating, preventing or treating or determining the predisposition to, disease and conditions of the breast, such as breast cancer" (see page 10 of the specification). However, the specification provides no evidence that

the sequences of SEQ ID NO: 1-14 are correlated with any type of disease or condition of the breast. There is no information provided in the specification regarding the level of expression of SEQ ID NO: 1-14 in any type of diseased breast tissue. The finding that mRNAs which hybridize to SEQ ID NO: 14 are more prevalent in breast tissue than in normal tissue does not indicate that such sequences are associated with diseases or conditions of the breast. Furthermore, the finding that mRNAs which hybridize to SEQ ID NO: 14 are more prevalent in breast tissue rather than normal tissues does not indicate that mRNAs which hybridize to any one of SEQ ID NO: 1-13 are also more prevalent in breast tissue because there is no evidence concerning the hybridization properties of the individual nucleotide fragments. The specification suggests that the claimed polynucleotide could be used for therapeutic purposes. Clearly, further research would be required to identify a disease for which the protein encoded by SEQ ID NO: 1-14 is involved and for which treatment with SEQ ID NO: 1-14 or any nucleic acid having 90% identity with SEQ ID NO: 1-14 would be effective or for which detection of SEQ ID NO: 1-14 expression would be informative. As stated in Brenner v. Manson, 383 U.S. 519 535-536, 148 USPQ 689, 696 (1966) " a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion". Support for an asserted utility that is specific and substantial would require, for example, a showing of a particular function for an encoded polypeptide. Merely identifying and studying the properties of a polypeptide or the diseases in which a polypeptide or polynucleotide may be involved does not constitute a "real world" context of use. Moreover, the use of the claimed polynucleotide to detect breast tissue is

considered to be a general use, rather than a specific use since tissue specific expression is a characteristic of a large genus of nucleic acids. Accordingly, the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility. Applicants attention is directed to the Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday January 5, 2001.

3. Claims 25-34 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial, or credible asserted utility or well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

RESPONSE TO ARGUMENTS:

In the response of Paper No. 26, filed March 20, 2002, Applicants traverse the 101 and 112, first paragraph (enablement) rejections by stating that the claimed sequences share sequence identity with GERP. Applicants filed a 132 Declaration showing a comparison between the nucleotide sequences of BS203 and GERP, a member of the RING finger family. The 132 Declaration states that the BS203 nucleic acid of SEQ ID NO: 14 shares 83.9% identity with the open reading frame of GERP. Applicants response further states that GERP is expressed in a variety of tumors, including adenocarcinomas and point out that adenocarcinomas comprise about 95% of breast malignancies (see Exhibit C of the response of Paper No. 22). Based on this information, Applicants conclude that "it is clear that BS203 exhibits utility as a diagnostic tool in detecting breast cancer."

Applicants arguments have been fully considered but are not persuasive because the finding that GERP is expressed in adenocarcinomas does not indicate that GERP nucleic acids can be used to diagnose adenocarcinomas or breast cancer. Vincent (Exhibit B, cited in the response of Paper No. 22) teaches that GERP is expressed in normal breast cells, as well as in normal brain, lung, placenta, kidney, muscle and germinal center B cells. The reference further teaches that GERP nucleic acids were also detected in a number of tumor cells including adenocarcinomas. The reference **does not teach** that there is a difference in the level of expression of GERP in normal breast cells versus adenocarcinoma or breast cancer cells. Thereby, Vincent does not teach that GERP nucleic acids can be used to diagnose adenocarcinomas or breast cancer. Accordingly, it is maintained that the specification has not established that the expression of the instantly claimed BS203 nucleic acids is correlated with breast cancer and has not adequately enabled one of skill in the art to use the claimed nuclei acids for the diagnosis of breast cancer.

4. Claims 25 and 28-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to polynucleotides comprising a sequence selected from the group consisting of SEQ ID NO: 1-13. The claims as broadly written include nucleic acids in which sequences are present flanking SEQ ID NO: 1-13. The broadest reasonable interpretation of the

claims indicates that the claims are inclusive of BS203 genes and BS203 genomic sequences. However, the specification does not teach any full length BS203 genes or any BS203 genomic sequences. The specification does not teach that any of the nucleic acids of SEQ ID NO: 1-13 span more than one exon, and thereby the claims as written include flanking intron sequences and full length gene sequences. Furthermore, the claims include nucleic acids which are defined only in terms of a small fragment. The claims do not define the sequence of the flanking nucleic acids, nor do the claims include functional language for the nucleic acids. In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". In analyzing whether the written description requirement is met for a genus claim, it is first determined whether a representative number of specifies have been described by their complete structure. In the instant case, the specification does not teach any intron or 5' regulatory or 3' untranslated sequences. The specification also does not teach any additional nucleic acids which comprise the fragments of SEQ ID NO: 1-13. It is then

determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (e.g. restriction map, chromosomal map position, biological activity of an encoded protein product, etc.). In the instant case, no such identifying characteristics have been provided for any of the polynucleotides. While at the time of filing applicants were in possession of polynucleotides consisting of SEQ ID NO: 1-14, the specification provides no information regarding genomic sequences surrounding the sequences of SEQ ID NO: 1-13. Furthermore, the specification does not identify any additional BS203 nucleic acids other than the consensus sequence of SEQ ID NO: 14. The limited information provided in the specification is not deemed sufficient to reasonably convey to one of skill in the art that Applicants were in possession of BS203 genomic sequences or nucleic acids comprising SEQ ID NO: 1-13. Therefore, the written description requirement has not been satisfied for the claims as they are broadly written. Applicants attention is drawn to the Guidelines for the Examination of Patent Applications under 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

RESPONSE TO ARGUMENTS:

In the response of Paper No. 26, Applicants traverse this rejection by stating that the claims have been amended and that claim 25 "is directed to certain isolated and purified sequences selected from the group consisting of SEQ ID NOS. Claim 32 is directed to a recombinant expression system comprising an isolated and purified nucleic acid selected from the group consisting of certain SEQ ID NOS". This argument is not convincing because

Applicant is arguing limitations that are not recited in the claims. The claims are not limited to nucleic acids consisting of SEQ ID NO: 1-14, but rather are drawn to nucleic acids **comprising** SEQ ID NO: 1-14. The term "comprising" is open, meaning that additional sequences may flank the recited nucleic acid. As discussed above, SEQ ID NO: 1-13 are fragments of the larger BS203 nucleic acid of SEQ ID NO: 14. Accordingly, the claims are inclusive of genomic sequences comprising SEQ ID NO: 1-13, variants of BS203 having any activity and novel nucleic acids comprising the fragments of SEQ ID NO: 1-13 and possible splice variants comprising the fragments of SEQ ID NO: 1-13. While the specification describes nucleic acids **consisting of** SEQ ID NO: 1-14, the specification does not adequately describe the claimed nucleic acids **comprising** SEQ ID NO: 1-13.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. The fax number for the Technology Center is (703)-305-3014 or (703)-305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers

July 29, 2002

Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER